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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/759,538

01/20/2004

Mitchell S. Steiner

P-5466-US

7110

49443 7590 05/09/2006

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EXAMINER

WEDDINGTON, KEVIN E

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 05/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/759,538

Applicant(s)

STEINER ET AL.

Examiner

Kevin E. Weddington

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-100 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-100 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Due to the complex nature of the claims, no request for an oral election is being made. Please see MPEP 812.01.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-8, 14-25 are drawn to a method of treating a female subject suffering from an Androgen Deficiency in Female (ADIF)-associated condition, said method comprising the step of administering to said subject a selective androgen receptor modulator (SARM) compound in an amount effective to treat said ADIF-associated condition, classified in class 514, subclasses 634 and 312.
- II. Claims 26-50 are drawn to a method of prevention, suppressing, inhibiting or reducing the incidence of an Androgen Deficiency in Female (ADIF)-associated condition, said method comprising the step of administering to said subject a selective androgen receptor modulator (SARM) compound in an amount effective to treat said ADIF-associated condition, classified in class 514, subclasses 634 and 312.
- III. Claims 51-75 are drawn to a method of treating a female subject suffering from sexual dysfunction, decreased sexual libido, hypogonadism, sarcopenia, osteopenia, osteoporosis, alterations in cognition and mood, fatigue, depression, anemia, muscle weakness, hair loss, obesity, polycystic ovarian disease, endometriosis, breast cancer,

Art Unit: 1614

uterine cancer or ovarian cancer due to Androgen Deficiency in Female (ADIF), said method comprising the step of administering to said subject a selective androgen receptor modulator (SARM) compound, classified in class 514, subclasses 634, 312, 909.

- IV. Claims 76-100 are drawn to a method of preventing, suppressing, inhibiting or reducing the incidence of an Androgen Deficiency in Female (ADIF)-associated condition selected from sexual dysfunction, decreased sexual libido, hypogonadism, sarcopenia, osteopenia, osteoporosis, alterations in cognition and mood, fatigue, depression, anemia, muscle weakness, hair loss, obesity, polycystic ovarian disease, endometriosis, breast cancer, uterine cancer or ovarian cancer, classified in class 514, subclasses 634, 312, 909.

The four inventions are independent and distinct, each from the other as they have a separate status in the art as shown by their different and separate subject matter for inventive effort. Further, a reference, which anticipates any one of the above inventions, would neither anticipate nor make obvious of the other inventions. Each such invention is capable of supporting its own patent. For these reasons, the restriction requirement is proper.

To be complete, applicants' response must include a provisional election even though the requirement may be traverse.

The applicants must also elect a species from formulae I-XI, for example, if the applicants elects Group II, they must elect a species from claims 28-38 (formulae I-XI)

Art Unit: 1614

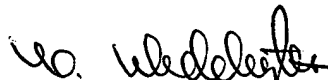
and from claims 39-45, what function the elected SARM is performing.

Note claims 9-13 are missing.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin E. Weddington whose telephone number is (571) 272-0587. The examiner can normally be reached on 12:00 am-8:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Kevin E. Weddington
Primary Examiner
Art Unit 1614

K. Weddington
May 4, 2006